

**REMARKS/ARGUMENTS**

This responds to the issues presented in the Office Action of March 18, 2011, a Final Rejection. It accompanies a Request for Continued Examination and a time extension.

The claims are amended: claim 16 is corrected and the limitation to components a and b forming the total amphiphilic components has been introduced. This later amendment is based upon the overall teaching of the application, upon the explicit disclosure at lines 9-13 of page 5, and upon the Examples as filed, which all relate to compositions in which the only amphiphilic components are DOPE and P80.

In the Office Action, the Examiner objects that claim 16 does not distinctly claim the invention because the number "50" was deleted without being replaced. The Examiner is thanked for proceeding on the logical assumption that this was simply an error and the enclosed claim set corrects this to read "60", as assumed.

The only substantive rejection relates to obviousness under 35 USC 103(a). In section 1, the Examiner rejects most claims as obvious over Liu in view of Unger and Landh. Key to this rejection is the disclosure of Liu of certain compositions in which quantities of DOPE and P80 are included in the proposed formulations (e.g. #17, 28 or #34). It has been surprisingly established by the present inventors that compositions of DOPE and P80 form non-lamellar phase structures having valuable properties in the absence of other amphiphilic components. This aspect is clearly demonstrated in the Examples of the application and is now claimed explicitly by the restriction of the claims to a) and b) being the total amphiphilic components.

It is notable that in all disclosures of Liu, comprise large proportions of the cationic lipid component DC-Chol (see Examples) and most also contain significant proportions of oils. The addition of P80 to these components is largely systematic, but the use of DOPE is entirely incidental to the formulations. In particular, there is no disclosure, teaching or suggestion of any formulation having DOPE and P80 as the sole amphiphilic components.

The Examiner argues that the present invention relates to the same components in the same form as Liu, and thus must inherently have the same properties. In view of the explicit limitation of the present claims to compositions having only DOPE and P80 as amphiphilic components, however, this cannot be the case; the present claims do not include the large proportions of DC-Chol and/or oil, which will have a major impact on the phase properties and

behaviors. Thus Liu cannot teach the compositions of the present invention nor have any bearing on their properties.

With regard to Unger, the Applicant maintains that the previously supplied extract from the "Language of shape" makes it clear that a micelle contains only lipid tails at its core. This is not the attorney's assertion but a documented feature taken from a standard text on the subject. It is furthermore evident that to form a liquid crystalline phase, some sort of boundary or heterogeneity must be present which can form such an ordered structure. This is evidently not present in simple hydrocarbon tail groups.

It is easy when immersed in the language of patent specifications to lose sight of the fact that "comprise" need not mean "contain". Although that is evidently a legitimate meaning of the term, and the most common usage in patent specifications, "comprise" can equally mean "to form or constitute", as evidenced by the attached dictionary extract. Thus there is no "evidence" in Unger that the specified hexagonal phase is formed within the micelles. This is solely the Examiner's reading of the extracted phrase. An equally valid reading of this phrase is that the micelles form a hexagonal phase and this is the interpretation supported by the evidence that micelles are *prima facie* incapable of forming internal structured phases for want of anything to arrange into a structure. Thus although arguments may not overcome evidence, there is in fact no evidence in Unger that hexagonal phases are formed within micelles rather than formed from them and there is clear evidence to the contrary.

With regard to section 2 of the Action, the Examiner rejects the remaining claims over Liu in view of Landh. Although the Examiner acknowledges that Liu does not indicate structures consisting of DOPE, P80 and a solvent, he indicates that such would be obvious because DOPE and P80 are disclosed in Landh. However, both P80 and DOPE are disclosed in Landh as additives for providing certain properties (such as affecting the *surface phase* in the case of DOPE). This is acknowledged by the Examiner who quotes Landh as disclosing DOPE in the context of controlling the surface phase.

In the present application, it is the interior phase which is to be non-lamellar, as indicated in the specification as filed. Furthermore, whatever the phase behavior, it is clear that Landh does not teach the use of DOPE or P80 in the absence of other components since you can neither impose a surface phase nor fragmentation upon nothing and must have a base material for these

additives to act upon. There are very many possible components disclosed in Landh. To choose any one to use arbitrarily is simply selecting from a "shopping list" of possibilities and since DOPE is disclosed only as an additive, there is no technical teaching that would motivate this selection. To choose two specific components to use in combination when these are not in any way emphasized or taught for individual or combined use is possible only with hindsight knowledge of the present invention and cannot be the act of a skilled worker without such information.

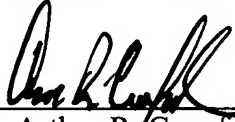
All outstanding issues have been addressed and this application is in condition for allowance. Should any minor issues remain outstanding, the Examiner should contact the undersigned at the telephone number listed below so they can be resolved expeditiously without need of a further written action.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1140.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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## comprise [kuh m-prahyz] ?

Origin

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## com·prise [kuh m-prahyz] ? Show IPA

**verb (used with object), -prised, -pris-ing.**

- to include or contain: *The Soviet Union comprised several socialist republics.*
- to consist of; be composed of: *The advisory board comprises six members.*
- to form or constitute: *Seminars and lectures comprised the day's activities.*

### Idiom

- be comprised of**, to consist of; be composed of: *The sales network is comprised of independent outlets and chain stores.*

Comprise is always a great word to know.  
So is component. Does it mean:

- ☐ constituent part or element
- ☐ related by blood

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### Origin:

1400-50; late Middle English *comprisen* < Middle French *compris* (past participle of *comprendre*) < Latin *comprehēnsus*; see *comprehension*

### Related forms

**com·pris-a-ble, adjective**  
**com·pris-al, noun**

**Can be confused:** compose, comprise, constitute (see usage note at the current entry).

### Synonyms

- See include.

### Usage note

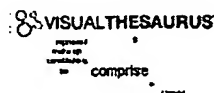
COMPRISE has had an interesting history of sense development. In addition to its original senses, dating from the 15th century, "to include" and "to consist of" (*The United States of America comprises 50 states*), COMPRISE has had since the late 18th century the meaning "to form or constitute" (*Fifty states comprise the United States of America*). Since the late 19th century it has also been used in passive constructions with a sense synonymous with that of one of its original meanings "to consist of, be composed of": *The United States of America is comprised of 50 states.*

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"Any adequate analysis or (if I may use the term) rational reconstruction of the method of science must **comprise** the statement that the scientist qua scientist accepts or rejects hypotheses; and further that an analysis of that statement would reveal it to entail that the scientist qua scientist makes value judgments."

-Richard Rudner

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